

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT KNOXVILLE

BRENDA DURHAM,)	
)	
<i>Plaintiff,</i>)	Case No. 3:20-CV-554
)	
v.)	Judge Collier
)	
JOHNSON & JOHNSON and)	Magistrate Judge Poplin
ETHICON, INC.,)	
)	
<i>Defendants.</i>)	

MEMORANDUM

Before the Court is a motion by Defendants, Johnson & Johnson and Ethicon, Inc., to dismiss the First Amended Complaint (Doc. 11) of Plaintiff, Brenda Durham, pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. (Doc. 18.) Plaintiff has filed a response in opposition (Doc. 21), as well as a supplemental brief (Doc. 23), and Defendants have replied (Doc. 22), as well as filed a response to Plaintiff's supplemental brief (Doc. 24). For the following reasons, the Court will **GRANT** Defendants' motion to dismiss (Doc. 18).

I. BACKGROUND

The following summary of the facts accepts all factual allegations in Plaintiff's First Amended Complaint (Doc. 11) as true. *See Gunasekera v. Irwin*, 551 F.3d 461, 466 (6th Cir. 2009).

A. Defendants' Pelvic-Mesh Product

Defendants designed, manufacture, and market the TVT-Obturator (the "TVT-O"), a pelvic-mesh product that is implanted in women who suffer from stress urinary incontinence to repair weakened or damaged tissue in the vagina. The TVT-O is made from polypropylene mesh and/or collagen. Polypropylene mesh is biologically incompatible with human tissue. As a result,

it degrades in tissue upon implantation, which can cause severe adverse reactions like inflammation of the pelvic tissue, nerve entrapment due to the contraction of the mesh, and chronic pain, among other issues. If the TVT-O is comprised of collagen, the collagen can disintegrate into a woman's pelvis, leading to the hardening of tissue, chronic pain, and fibrotic reaction.

The use of polypropylene mesh and collagen make the TVT-O defective. But the product also is defective due to where it is inserted in the tissue; biomechanical issues that cause the mesh to contract; its propensity for plastic deformation, rigidity, and inflexibility; degradation and fragmentation; and the difficulty of its removal. Defendants are aware of these defects and the risks associated with them. Even so, Defendants market the TVT-O to healthcare providers and patients as a device that can be implanted through a minimally invasive procedure and that results in minimal local tissue reactions and trauma.

The Food and Drug Administration (the "FDA") had previously cleared the TVT-O for sale in the United States, although such clearance did not require Defendants to prove the safety and efficacy of the product. However, on October 20, 2008, the FDA issued a notification regarding over a thousand complaints regarding pelvic-mesh products, including the TVT-O. On July 13, 2011, the FDA issued a warning for serious complications associated with pelvic-mesh products used for pelvic organ prolapse ("POP") repair, which use the same mesh as the TVT-O.

On April 16, 2019, the FDA ordered all transvaginal POP device manufacturers to stop selling and distributing their POP products. As of February 17, 2021, the FDA has not banned the sale and distribution of Defendants' TVT-O, although the TVT-O uses the same mesh as the POP devices. To this day, Defendants market the TVT-O to the medical community and patients as a safe, effective, and reliable medical device.

B. Plaintiff's TVT-O Implant

On October 12, 2011, Plaintiff was implanted with a TVT-O by Dr. Lee Congleton, III, in Knoxville, Tennessee. At some point after the implant, Plaintiff developed complications from her TVT-O and experienced pelvic pain, pelvic relaxation, mixed incontinence, hesitancy, frequency, and dyspareunia. Plaintiff has sought medical treatment for these complications and likely will need to do so in the future as well.

C. Procedural History

On December 30, 2020, Plaintiff filed this lawsuit against Defendants. (Doc. 1.) On February 17, 2021, Plaintiff filed her First Amended Complaint, asserting ten claims against Defendants: (1) general negligence, failure to warn or instruct, negligent infliction of emotional distress, and gross negligence under the Tennessee Products Liability Act (the "TPLA"), Tenn. Code Ann. §§ 29-28-101, *et seq.*; (2) negligent misrepresentation; (3) strict liability due to design defect, manufacturing defect, failure to warn, and defective product under the TPLA; (4) breach of express warranty; (5) breach of implied warranty under the TPLA; (6) fraud; (7) constructive fraud; (8) fraudulent concealment under the TPLA; (9) unjust enrichment under the TPLA; and (10) punitive damages. (Doc. 11 ¶¶ 76–191.)

Defendants move to dismiss the First Amended Complaint under Rule 12(b)(6) of the Federal Rules of Civil Procedure. (Doc. 18.) As an initial matter, Defendants contend Plaintiff's claims must be dismissed due to her failure to conform those claims with the TPLA, specifically that she pleaded them as separate counts. (Doc. 19 at 3–5.) Alternatively, Defendants argue Plaintiff has failed to state any claim for relief, as she fails to plausibly allege the elements of a TPLA claim for three reasons. (*Id.* at 6–20.) First, Defendants assert Plaintiff's allegations of design defect are vague and conclusory and fail to allege causation. (*Id.* at 6–9.) Second,

Defendants argue Plaintiff has not alleged a manufacturing defect because she has not alleged either causation or how the manufacturing of her TVT-O deviated from other TVT-Os. (*Id.* at 9–10.) Third, Defendants contend Plaintiff’s failure-to-warn theory fails because she does not plead how the warnings were inadequate or how the inadequate warnings injured her. (*Id.* at 10–12.) Alternatively, Defendants argue some of Plaintiff’s claims fail on additional grounds other than the TPLA. (*Id.* at 12–20.) Finally, Defendants assert Plaintiff’s claim for punitive damages should be dismissed because it is not an independent cause of action under Tennessee law. (*Id.* at 20.)

Plaintiff has responded in opposition, arguing she has pleaded claims consistent with the TPLA and has discretion to assert separate TPLA claims. (Doc. 21 at 3–4.) Plaintiff also contends she has alleged plausible claims based on design defect, manufacturing defect, and failure to warn. (*Id.* at 4–6.) Plaintiff argues several of her claims are not subsumed by the TPLA and she has adequately pleaded those claims. (*Id.* at 6–12.) In addition, Plaintiff asserts Tennessee recognizes a claim for punitive damages as a separate claim. (*Id.* at 12–13.) Finally, Plaintiff asks the Court for leave to file an amended complaint if it finds Defendants’ motion meritorious. (*Id.* at 13.)

Defendants have filed a reply, in which they reiterate their principal arguments for dismissal. (Doc. 22.) Plaintiff has filed a supplemental brief addressing a recent decision from the United States District Court for the Western District of Oklahoma (Doc. 23), to which Defendants filed a reply (Doc. 24).

Defendants’ motion to dismiss is now ripe for review.

II. STANDARD OF REVIEW

A party may move to dismiss a claim for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). In deciding a Rule 12(b)(6) motion to dismiss, a court first must accept all factual allegations of the complaint as true and construe the complaint in the light most

favorable to the plaintiff. *See Grindstaff v. Green*, 133 F.3d 416, 421 (6th Cir. 1998). All ambiguities must be resolved in the plaintiff's favor. *Carter by Carter v. Cornwell*, 983 F.2d 52, 54 (6th Cir. 1993) (citing *Jackson v. Richards Med. Co.*, 961 F.2d 575, 577 (6th Cir. 1992)). Bare legal conclusions, however, need not be accepted as true. *See Papasan v. Allain*, 478 U.S. 265, 286 (1986).

After assuming the veracity of factual allegations and construing ambiguities in the plaintiff's favor, the Court then must determine whether those allegations "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Sufficient factual allegations are pleaded when a court is able "to draw the reasonable inference that the defendant is liable for the misconduct alleged" and there is "more than a sheer possibility that a defendant has acted unlawfully." *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). To determine whether the complaint states a plausible claim on its face, a court must "draw on its judicial experience and common sense." *See id.* at 679.

III. DISCUSSION

As an initial matter, the parties dispute the effect of the TPLA on Plaintiff's claims. Defendants argue all of Plaintiff's claims are subsumed by the TPLA (Doc. 19 at 3–5), while Plaintiff asserts that some of her claims, but not all, are governed by the TPLA (Doc. 21 at 3–4).

This dispute is just one of semantics. The TPLA covers Plaintiff's products-liability claims, not "subsumes" them. A "product liability action" under the TPLA includes all actions based on:

strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge duty to warn or instruct, whether negligent, or innocent; misrepresentation, concealment, or nondisclosure, whether negligent, or innocent; or under any other substantive legal theory in tort or contract whatsoever.

Tenn. Code Ann. § 29-28-102(6). “Courts applying Tennessee law have routinely held that the term ‘products liability action’ is cast so expansively as to cover claims related to a defective product under legal theories of many kinds, whether sounding in negligence, misrepresentation, or breach of warranty.” *Strayhorn v. Wyeth Pharms., Inc.*, 882 F. Supp. 2d 1020, 1028 (W.D. Tenn. 2012); *see also Meadow v. NIBCO, Inc.*, No. 3-15-1124, 2016 WL 2986350, at *1 (M.D. Tenn. May 24, 2016) (“The TPLA governs [Plaintiff’s] claims because the TPLA embraces all product liability theories under Tennessee law.”).

The Court finds Counts One to Nine of the First Amended Complaint are covered by the TPLA.¹ *See Fleming v. Janssen Pharms., Inc.*, 186 F. Supp. 3d 826, 836 (W.D. Tenn. 2016) (finding the plaintiff’s claims for “fraud are encompassed within the scope of actions under the TPLA”); *Orr v. Ethicon, Inc.*, No. 2:20-CV-110-TAV-HBG, 2020 WL 9073528, at *2 (E.D. Tenn. Sept. 11, 2020) (finding the plaintiff’s claim for unjust enrichment was governed by TPLA). Therefore, initially, Plaintiff must plausibly allege the elements of a TPLA claim for these counts. *See Maness v. Boston Scientific*, 751 F. Supp. 2d 962, 968 (E.D. Tenn. 2010). The Court first turns to Plaintiff’s claims covered by the TPLA and then to her claim for punitive damages.

¹ Defendants argue the Court should dismiss Plaintiff’s products-liability claims due to her failure to plead them as a single TPLA claim (Doc. 19 at 3–5), while Plaintiff argues she is free to assert her claims under the TPLA individually (Doc. 21 at 3–4). There is authority to support both positions. *Compare Meadow v. NIBCO, Inc.*, No. 3-15-1124, 2016 WL 2986350, at *2 (M.D. Tenn. May 24, 2016) (instructing the plaintiff to file amended complaint to assert “his various theories under a single TPLA claim”) with *Webb v. Ethicon, Inc.*, No. 3:19-cv-461-TAV-DCP, 2020 WL 5503646, at *4 (E.D. Tenn. Sept. 11, 2020) (acknowledging a TPLA plaintiff could “bring multiple claims or one TPLA claim on multiple theories”). The Court, however, is aware of no authority to support Defendants’ proposition that failure to plead claims covered by the TPLA as a single claim warrants dismissal. The Court declines to do so here, especially considering “the plaintiff is the master of [her] complaint.” *See Loftis v. United Parcel Serv., Inc.*, 342 F.3d 509, 515 (6th Cir. 2003) (quoting *Alexander v. Elec. Data Sys. Corp.*, 13 F.3d 940, 943 (6th Cir. 1994)).

A. TPLA Claims (Counts I–IX)

The TPLA does not impose liability on “[a] manufacturer or seller of a product . . . for any injury to a person . . . caused by the product unless the product is determined to be in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.” Tenn. Code Ann. § 29-28-105(a). A prima facie product-liability claim exists if the plaintiff shows three elements: “(1) the product was defective and/or unreasonably dangerous, (2) the defect existed at the time the product left the manufacturer’s control, and (3) the plaintiff’s injury was proximately caused by the defective product.” *Sigler v. Am. Honda Motor Co.*, 532 F.3d 469, 483 (6th Cir. 2008) (internal quotation omitted). These elements are the same regardless of the legal theory or theories on which the plaintiff relies. *See Tatham v. Bridgestone Ams. Holdings, Inc.*, 473 S.W.3d 734, 749 (Tenn. 2015).

The Court need only address the third element, as Plaintiff fails to allege causation and therefore fails to state any TPLA claim. “Causation is an essential element of the Plaintiff’s claim, whether establishing that the product was defective or unreasonably dangerous.” *Id.* at 751. “[I]t is not enough that plaintiff suffered injuries from using (or in this case, having implanted) a product.” *Moore v. C.R. Bard, Inc.*, 217 F. Supp. 3d 990, 995 (E.D. Tenn. 2016). Rather, there must be “a showing that the *particular* defect or dangerous condition proximately caused the plaintiff’s injury,” or the manufacturer cannot be liable. *Jackson v. Ford Motor Co.*, 842 F.3d 902, 907 (6th Cir. 2016) (emphasis added) (quoting *King v. Danek Med., Inc.*, 37 S.W.3d 429, 435 (Tenn. Ct. App. 2000)); *see also Maness*, 751 F. Supp. 2d at 970–71 (“[T]he issue is whether the alleged *defective design or manufacturing* of the [product] caused her pain.”).

Plaintiff alleges at least ten defects as to the TVT-O. (*See, e.g.*, Doc. 11 ¶ 53(a)–(j).) But to show causation, she must put forth factual allegations that allow the Court to infer that at least

one of those defects caused her injuries. *See Jackson*, 842 F.3d at 907. She has not done so for two, albeit related, reasons.

First, Plaintiff does not allege which, if any, defects in her implanted TVT-O actually caused her injuries. Instead, Plaintiff alleges:

Defendants' TVT-O product that was implanted in Plaintiff exhibited *some or all* of the aforementioned defects as described herein. The specific defects of the TVT-O device that Plaintiff was implanted with are the direct and proximate causes of her injuries as described herein.

(Doc. 11 ¶ 110 (emphasis added).) This vague allegation asks the Court to “simply rely on [Plaintiff’s] allegation that” one of the defects caused her injuries. *See Tilden v. Gen. Elec. Co.*, No. 3:11-CV-628, 2012 WL 1023617, at *4 (E.D. Tenn. Mar. 26, 2012). Doing so fails to satisfy Rule 12(b)(6). *See Iqbal*, 556 U.S. at 678 (holding the plaintiff must allege facts demonstrating “more than a sheer possibility that a defendant has acted unlawfully”).²

Second, and similarly, Plaintiff fails to allege how her TVT-O actually caused her specific injuries. A plaintiff must “trace [her] injury to the specific defect.” *Moore*, 217 F. Supp. 3d at 994 (quoting *King*, 37 S.W.3d at 435). None of Plaintiff’s allegations do so, as she alleges just that she “subsequently developed complications arising from the implant of [the TVT-O], including, but not limited to: mesh implant complications necessitating removal, pelvic pain, pelvic relaxation, worsening mixed incontinence, hesitancy, frequency, and dyspareunia.” (Doc. 11 ¶ 3.) “Instead of describing ‘how’ the injury occurred, Plaintiff simply concludes that the [TVT-O] was ‘the sole, direct and proximate cause of’” her injuries. *See Brewer v. Mr. Heater, Inc.*, No. 13-1330, 2014 WL 1364825, at *3 (W.D. Tenn. Apr. 7, 2014). For example, she alleges:

As a direct and proximate result of the TVT-O products’ aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain

² In fact, the First Amended Complaint lacks even basic details about Plaintiff’s alleged injuries, such as when she discovered them or the medical procedures she underwent to treat them.

and suffering, has sustained permanent injury, has undergone medical treatment and corrective surgery and hospitalization, has suffered financial and economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

(Doc. 11 ¶ 104; *see also id.* ¶¶ 58, 69, 114.) These allegations of causation are bare legal conclusions that the Court is instructed not to accept as true. *See Papasan*, 478 U.S. at 286. Thus, Plaintiff has not “allege[d] facts that indicate how the alleged defect(s) caused [her] injuries.” *See Fleming*, 186 F. Supp. 3d at 835; *see, e.g., Tilden*, 2012 WL 1023617, at *5.

As to her failure-to-warn theory, Plaintiff likewise fails to allege causation. *See Moore*, 217 F. Supp. 3d at 995 (explaining element of failure-to-warn claim under TPLA is that “the inadequate labeling proximately caused the claimed injury”). When a plaintiff relies on the learned-intermediary doctrine, as Plaintiff does here (*see* Doc. 21 at 5), “[a]ll Tennessee law requires is evidence that a warning would have altered the doctor’s actions and that the change in the doctor’s actions would have averted the patient’s injury.” *See Payne v. Novartis Pharm. Corp.*, 767 F.3d 526, 531 (6th Cir. 2014). Plaintiff alleges her physicians “would not . . . [have] utilized the TVT-O pelvic mesh product for treatment of Plaintiff’s stress urinary incontinence” if they had been warned of the TVT-O’s risks. (Doc. 11 ¶ 67.) However, as discussed above, no allegations establish these actions would have avoided Plaintiff’s injuries, as Plaintiff fails to connect her injuries to her TVT-O or its alleged defects. Thus, the First Amended Complaint fails to set forth factual allegations of proximate causation for Plaintiff’s failure-to-warn theory under the TPLA.

In sum, Plaintiff has failed to allege causation, which means her claims covered by the TPLA must fail. Accordingly, the Court will **GRANT** Defendants’ motion to dismiss (Doc. 18) and **DISMISS WITH PREJUDICE** Counts One to Nine of Plaintiff’s Amended Complaint.

B. Claim for Punitive Damages (Count X)

Plaintiff's only remaining claim, Count Ten, is her claim for punitive damages. (See Doc. 11 ¶¶ 168–91.) Defendants contend Tennessee does not recognize an independent cause of action for punitive damages (Doc. 19 at 20), but Plaintiff argues otherwise (Doc. 21 at 13).

To an extent, both parties are correct. Tennessee courts have recognized a claim for punitive damages as a separate cause of action; however, “it is well-settled that a party is entitled to punitive damages only if it recovers actual damages.” *Bogle ex rel. Bogle v. Nighthawk Radiology Servs., LLC*, No. M2014-01933-COA-R3-CV, 2016 WL 1398931, at *12 (Tenn. Ct. App. Apr. 6, 2016); see also *JWT, L.P. v. Printers Press, Inc.*, No. M2001-02590-COA-R3-CV, 2002 WL 31397317, at *8 (Tenn. Ct. App. Oct. 24, 2002). A claim for punitive damages therefore depends on actual damages being recoverable or “a basis for the recovery of compensatory damages.” *Beal v. Walgreen Co.*, No. W2004-02925-COA-R3-CV, 2006 WL 59811, at *12 (Tenn. Ct. App. Jan. 12, 2006) (quoting 25 C.J.S. *Damages* § 197 (2002)); see also *Liberty Mut. Ins. Co. v. Stevenson*, 368 S.W.2d 760, 761 (Tenn. 1963) (“For one to obtain [punitive damages] it is necessary . . . that a predicate must have first been laid wherein actual damages have been awarded.”); *Jenkins v. Brown*, No. M2005-02022-COA-R3-CV, 2007 WL 4372166, at *13 (Tenn. Ct. App. Dec. 14, 2007) (“In Tennessee, there can be no claim for punitive damages alone. Thus, without an award of compensatory damages or any other sort of remedial relief, an award of punitive damages cannot stand.”).³

³ There appears to be one exception to this general rule: “[w]here the plaintiff has proved an entitlement to injunctive relief, an award of punitive damages may be upheld without an award of compensatory damages.” See *Oakley v. Simmons*, 799 S.W.2d 669, 672 (Tenn. Ct. App. 1990). The exception cannot apply to this case, however, as Plaintiff does not seek injunctive relief. (See Doc. 11 at 52.)

Because Plaintiff's other claims have been dismissed, *see supra* § III.A, she cannot recover actual or compensatory damages from Defendants. Under Tennessee law, Plaintiff therefore also cannot recover punitive damages from Defendants. *See, e.g., Beal*, 2006 WL 59811, at *6 (declining to remand punitive-damages issue to the trial court, in part, because "all causes of action which supported an award for compensatory damages" had been dismissed). The Court will **GRANT** Defendants' motion to dismiss (Doc. 18) and **DISMISS WITH PREJUDICE** Count Ten of Plaintiff's Amended Complaint.

C. Plaintiff's Request for Leave to File Second Amended Complaint

Plaintiff asks the Court to grant her leave to file a second amended complaint in the event it finds merit in Defendants' motion to dismiss. (Doc. 21 at 13.) Pursuant to Rule 15 of the Federal Rules of Civil Procedure, a court may grant leave to amend "when justice so requires." Fed. R. Civ. P. 15(a). Courts must read Rule 15 in conjunction with Rule 7(b), which requires that a party make such a request in a motion that states with "particularity the grounds for seeking the order." Fed. R. Civ. P. 7(b); *see also Evans v. Pearson Enter., Inc.*, 434 F.3d 839, 853 (6th Cir. 2006). In addition, the Local Rules of this Court state that "[a] party who moves to amend a pleading shall attach a copy of the proposed amended pleading to the motion" and "failure to comply with this rule may be grounds for denial of the motion." E.D. Tenn. L.R. 15.1. The Court of Appeals for the Sixth Circuit does not look favorably upon bare requests for leave to amend in a response to a motion to dismiss when the requesting party could have filed a proper motion to amend and attached a proposed amended complaint for consideration by the court. *See, e.g., Evans*, 434 F.3d at 853; *see also Begala v. PNC Bank, Ohio, Nat'l Ass'n*, 214 F.3d 776, 783–84 (6th Cir. 2000).

Plaintiff has failed to follow the proper procedure to file a second amended complaint. She not only has failed to file a motion to amend, but also has not attached a copy of the proposed

amended pleading to the motion, as required by the Local Rules. *See* E.D. Tenn. L.R. 15.1. The Court has no means by which to decide whether Plaintiff's amendment would be futile or resolve the deficiencies addressed above. *See Hageman v. Signal L. P. Gas, Inc.*, 486 F.2d 479, 484 (6th Cir. 1973). Therefore, the Court declines to provide Plaintiff leave to file a second amended complaint.

IV. CONCLUSION

For the foregoing reasons, the Court will **GRANT** Defendants' motion to dismiss (Doc. 18) and **DISMISS WITH PREJUDICE** Plaintiff's Amended Complaint.

AN APPROPRIATE ORDER WILL ENTER.

/s/
CURTIS L. COLLIER
UNITED STATES DISTRICT JUDGE